1	<u>CLAIMS</u>
2	What is Claimed Is:
3	
4	Claim 1. A method for treating a patient suffering from a cancerous disease
5	comprising:
6	administering to said patient an anti-cancer antibody or fragment thereof produced
7	in accordance with a method for the production of anti-cancer antibodies which are useful
8	in treating a cancerous disease, said antibody or fragment thereof characterized as being
9	cytotoxic against cells of a cancerous tissue, and being essentially benign to non-cancerous
10	cells;
11	wherein said antibody or fragment thereof is placed in admixture with a
12	pharmaceutically acceptable adjuvant and is administered in an amount effective to
13	mediate treatment of said cancerous disease;
14	said antibody being an isolated monoclonal antibody or antigen binding fragment
15	thereof which binds to an antigenic moiety expressed by said cancerous tissue, said
16	antigenic moiety characterized as being bound by an antibody having identifying
17	characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as
18	PTA-4621.
19	
20	Claim 2. The method for treating a patient suffering from a cancerous disease
21	in accordance with claim 1, wherein said antibody or fragment thereof is humanized or
22	chimerized.

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2	Claim 3. The method for treating a patient suffering from a cancerous disease
3	in accordance with claim 1 comprising:
4	conjugating said antibody or antigen binding fragment thereof with a member
5	selected from the group consisting of toxins, enzymes, radioactive compounds, and
6	hematogenous cells, thereby forming an antibody conjugate; and
7	administering said antibody conjugate or conjugated fragments thereof to said
8	patient;
9	wherein said antibody conjugate or conjugated fragments are placed in admixture
10	with a pharmaceutically acceptable adjuvant and are administered in an amount effective to
11	mediate treatment of said cancerous disease.
12	
13	Claim 4. The method of claim 3, wherein said antibody or fragment thereof is
14	humanized or chimerized.
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16	Claim 5. The method for treating a patient suffering from a cancerous disease in
17	accordance with claim 1 wherein:
18	the cytotoxicity of said antibody or fragment thereof is mediated through antibody
19	dependent cellular toxicity.
20	
21	Claim 6. The method for treating a patient suffering from a cancerous disease in
22	accordance with claim 1 wherein:

1	the cytotoxicity of said antibody or fragment thereof is mediated through
2	complement dependent cellular toxicity.
3	
4	Claim 7. The method for treating a patient suffering from a cancerous disease in
5	accordance with claim 1 wherein:
6	the cytotoxicity of said antibody or fragment thereof is mediated through catalyzing
7	of the hydrolysis of cellular chemical bonds.
8	
9	Claim 8. The method for treating a patient suffering from a cancerous disease in
10	accordance with claim 1 wherein:
11	the cytotoxicity of said antibody or fragment thereof is mediated through producing
12	an immune response against putative cancer antigens residing on tumor cells.
13	
14	Claim 9. The method for treating a patient suffering from a cancerous disease in
15	accordance with claim 1 wherein:

1	the cytotoxicity of said antibody or fragment thereof is mediated through
2	targeting of cell membrane proteins to interfere with their function.
3	
4	Claim 10. The method for treating a patient suffering from a cancerous disease
5	in accordance with claim 1 wherein:
6	the cytotoxicity of said antibody or fragment thereof is mediated through
7	production of a conformational change in a cellular protein effective to produce a
8	signal to initiate cell-killing.
9	
10	Claim 11. The method for treating a patient suffering from a cancerous
11	disease in accordance with claim 1 wherein:
12	said method of production utilizes a tissue sample containing cancerous and
13	non-cancerous cells obtained from a particular individual.
14	
15	Claim 12. A method for treating a patient suffering from a cancerous
16	disease comprising:
17	administering to said patient an antibody or antigen binding fragment thereof
18	produced in accordance with a method for the production of anti-cancer antibodies
19	which are useful in treating a cancerous disease, said antibody being cytotoxic against
20	cells of a cancerous tissue, and essentially benign to non-cancerous cells;
21	wherein said antibody is the isolated monoclonal antibody encoded by the clone
22	deposited with the ATCC as PTA-4621 or an antigen binding fragment thereof, and is
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1	placed in admixture with a pharmaceutically acceptable adjuvant and is administered in
2	an amount effective to mediate treatment of said cancerous disease.
3	
4	Claim 13. The method for treating a patient suffering from a cancerous
5	disease in accordance with claim 12, wherein said antibody or fragment thereof is
6	humanized or chimerized.
7	
8	Claim 14. The method for treating a patient suffering from a cancerous
9	disease in accordance with claim 12 comprising:
10	conjugating said antibody or fragment thereof with a member selected from the
11	group consisting of toxins, enzymes, radioactive compounds, and hematogenous cells
12	whereby an antibody conjugate is formed; and
13	administering said antibody conjugates or fragments thereof to said patient;
14	wherein said conjugated antibodies are placed in admixture with a
15	pharmaceutically acceptable adjuvant and are administered in an amount effective to
16	mediate treatment of said cancerous disease.
17	Claim 15. The method of claim 14, wherein said antibody or fragmen
18	thereof is selected from said subset are humanized or chimerized.
19	
20	Claim 16. The method for treating a patient suffering from a cancerous disease
21	in accordance with claim 12 wherein:

1	the cytotoxicity of said antibody or fragment thereof is mediated through
2	antibody dependent cellular toxicity.
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4	Claim 17. The method for treating a patient suffering from a cancerous disease
5	in accordance with claim 12 wherein:
6	the cytotoxicity of said antibody or fragment thereof is mediated through
7	complement dependent cellular toxicity.
8	
9	Claim 18. The method for treating a patient suffering from a cancerous disease
10	in accordance with claim 12 wherein:
11	the cytotoxicity of said antibody or fragment thereof is mediated through
12	catalyzing of the hydrolysis of cellular chemical bonds.
13	
14	Claim 19. The method for treating a patient suffering from a cancerous disease
15	in accordance with claim 12 wherein:
16	the cytotoxicity of said antibody or fragment thereof is mediated through
17	producing an immune response against putative cancer antigens residing on tumor
18	cells.
19	
20	Claim 20. The method for treating a patient suffering from a cancerous disease
21	in accordance with claim 12 wherein:

1	the cytotoxicity of said antibody or fragment thereof is mediated through
2	targeting of cell membrane proteins to interfere with their function.
3	
4	Claim 21. The method for treating a patient suffering from a cancerous disease
5	in accordance with claim 12 wherein:
6	the cytotoxicity of said antibody or fragment thereof is mediated through
7	production of a conformational change in a cellular protein effective to produce a
8	signal to initiate cell-killing.
9	
10	Claim 22. The method for treating a patient suffering from a cancerous
11	disease in accordance with claim 12 wherein:
12	said method of production utilizes a tissue sample containing cancerous and
13 14	non-cancerous cells obtained from a particular individual.
15	Claim 23. A process for mediating cytotoxicity of a human tumor cell
16	which expresses a CD44 antigenic moiety on the cell surface comprising:
17	contacting said tumor cell with an isolated monoclonal antibody or
18	antigen binding fragment thereof, said antibody or antigen binding fragment thereof
19	being an isolated monoclonal antibody or antigen binding fragment thereof which
20	binds to said expressed CD44 antigenic moiety, said antigenic moiety characterized as
21	being bound by an antibody having the identifying characteristics of a monoclonal
22	antibody encoded by the clone deposited with the ATCC as PTA-4621,

1	whereby cell cytotoxicity occurs as a result of said binding.
2	
3	Claim 24. The process of claim 23 wherein said isolated antibody or
4	antigen binding fragments thereof are humanized or chimerized.
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6	Claim 25. The process of claim 23 wherein said isolated antibody or
7	antigen binding fragments thereof are conjugated with a member selected from the
8	group consisting of cytotoxic moieties, enzymes, radioactive compounds, and
9	hematogenous cells, whereby an antibody conjugate is formed
10	
11	Claim 26. The process of claim 23 wherein said isolated antibody or
12	antigen binding fragments thereof are humanized or chimerized.
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14	Claim 27. The process of claim 23 wherein said isolated antibody or
15	antigen binding fragments thereof are murine.
16	
17	Claim 28. The process of claim 23 wherein the human tumor tissue sample
18	is obtained from a tumor originating in a tissue selected from the group consisting of
19	colon, ovarian, lung, prostate and breast tissue.
20	
21	Claim 29. A binding assay to determine a presence of cells which express a
22	CD44 antigenic moiety which specifically binds to an isolated monoclonal antibody McHale & Slavin, P.A. 52 2056.000025

1	encoded by the clone deposited with the ATCC as PTA-4621 or an antigen binding
2	fragment thereof comprising:
3	providing a cell sample;
4	providing an isolated monoclonal antibody or antigen binding fragment thereof,
5	said antibody or antigen binding fragment thereof being an isolated monoclonal
6	antibody or antigen binding fragment thereof which binds to said expressed CD44
7	antigenic moiety, said antigenic moiety characterized as being bound by an antibody
8	having the identifying characteristics of a monoclonal antibody encoded by the clone
9	deposited with the ATCC as PTA-4621;
10	contacting said isolated monoclonal antibody or antigen binding fragment
11	thereof with said cell sample; and
12	determining binding of said isolated monoclonal antibody or antigen binding
13	fragment thereof with said cell sample;
14	whereby the presence of cells which express a CD44 antigenic moiety which
15	specifically binds to said isolated monoclonal antibody or antigen binding fragment
16	thereof is determined.
17	Claim 30. The binding assay of claim 29 wherein the cell sample is
18	obtained from a tumor originating in a tissue selected from the group consisting of
19	colon, ovarian, lung, prostate and breast tissue.
20	
21	Claim 31. A process of isolating or screening for cells in a sample which
22	express a CD44 antigenic moiety which specifically binds to an isolated monoclonal McHale & Slavin, P.A. 53 2056.000025

1	antibody or antigen binding fragment thereof, said antigenic moiety characterized as
2	being bound by an antibody having the identifying characteristics of a monoclonal
3	antibody encoded by the clone deposited with the ATCC as PTA-4621 comprising:
4	providing a cell sample;
5	providing an isolated monoclonal antibody or antigen binding fragment thereof,
6	said antibody or antigen binding fragment thereof being an isolated monoclonal
7	antibody or antigen binding fragment thereof which binds to said expressed CD44
8	antigenic moiety, said antigenic moiety characterized as being bound by an antibody
9	having the identifying characteristics of a monoclonal antibody encoded by the clone
10	deposited with the ATCC as PTA-4621;
11	contacting said isolated monoclonal antibody or antigen binding fragment
12	thereof with said cell sample; and
13	determining binding of said isolated monoclonal antibody or antigen binding
14	fragment thereof with said cell sample;
15	whereby said cells which express a CD44 antigenic moiety which specifically
16	binds to an isolated monoclonal antibody encoded by the clone deposited with the
17	ATCC as PTA-4621, or antigen binding fragment thereof are isolated by said binding
18	and their presence in said cell sample is confirmed.
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20	Claim 32. The process of claim 31 wherein the cell sample is obtained
21	from a tumor originating in a tissue selected from the group consisting of colon,
22	ovarian, lung, prostate and breast tissue.
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2	Claim 33. A method of extending survival and/or delaying disease progression
3	by treating a human tumor in a mammal, wherein said tumor expresses an antigen
4	which specifically binds to a monoclonal antibody or antigen binding fragment thereof
5	which has the identifying characteristics of a monoclonal antibody encoded by a clone
6	deposited with the ATCC as accession number PTA-4621 comprising administering to
7	said mammal said monoclonal antibody in an amount effective to reduce said
8	mammal's tumor burden, whereby disease progression is delayed and/or survival is
9	extended.
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11	Claim 34. The method of claim 33 wherein said antibody is conjugated to a
12	cytotoxic moiety.
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14	Claim 35. The method of claim 33 wherein said cytotoxic moiety is a
15	radioactive isotope.
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17	Claim 36. The method of claim 33 wherein said antibody activates complement.
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19	Claim 37. The method of claim 33 wherein said antibody mediates antibody
20	dependent cellular cytotoxicity.
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22	Claim 38. The method of claim 33 wherein said antibody is a murine antibody.
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1	Claim 39. The method of claim 33 wherein said antibody is a numanized
2	antibody
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4	Claim 40. The method of claim 33 wherein said antibody is a chimerized
5	antibody.
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